K102752

NOV - 9 2011

Exhibit 5: 510(K) Summary

510(K) Summary
Prepared August 15, 2010

STINGRAY SURGICAL PROUCTS INC
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Contact Brian McBrinn, Regulatory Affairs

1. Identification of the Device:
   Proprietary-Trade Name: Stingray Ultralite Disposable Irrigation Bipolar Forceps
   Classification Name: Electrosurgical cutting and coagulation device and accessories
   Product Codes Product Code GEI
   Common/Usual Name: Bipolar Forceps Single Use

2. Equivalent legally marketed devices: Stingray Ultralite Disposable Irrigation Forceps are substantially equivalent to Olsen Medical Single Use Bayonet Bipolar Irrigating Forceps K080187 and Stingray Electrosurgical Forceps K083162 based on the device similarity to predicated device.

3. Indications for Use (intended use) Designed to grasp, manipulate and coagulate selected tissue for single use in general surgical procedures. These forceps can be sold with or without irrigation amd are provided sterile. They are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator and irrigation module. Stingray Ultralite Disposable Irrigation Forceps can be used with bipolar coagulation current. Coagulation is achieved using electrosurgical energy generated by the electro surgical generator unit and activated by a footswitch. The Stingray Ultralite Disposable Irrigation Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

4. Description of the Device: These devices are disposable bipolar forceps design for single use in general surgical procedures. They are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. The forceps are designed to grasp and manipulate, or irrigate selected tissues. The semi rigid irrigation tube is designed to carry nonpyrogenic fluid through the instrument and outputted to the tip end. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator unit and activated by a footswitch. They are constructed of stainless steel, a nylon coating, and a non-stick alloy tip. The devices are provided sterile ethylene oxide (ETO) and in sterile packs.

5. Safety and Effectiveness, comparison to predicate device, Stingray Ultralite Disposable Irrigation Forceps were designed and manufactured to the same specifications as Stingray

5. Safety and Effectiveness, comparison to predicate device, Stingray Ultralite Disposable Irrigation Forceps were designed and manufactured to the same specifications as Stingray Electrosurgical Forceps K083162, which have been subject to bench and standards testing indicating the device is safe and effective. They have been designed to meet or exceed ANSI/AAMI HF18-2001 and IEC 60601-2-2:2006 voluntary standards. Since the new device is manufactured by the same company in the same way as the new device, it is as safe and effective as the predicate device.

6. Substantial Equivalence Chart

Charateristic	**Description of Stingray Ultralite Irrigating Forceps**	**Olsen Medical Single Use Bayonet Bipolar Irrigating Forceps K080187**	**Stingray Electrosurgical Forceps K083162**
Intendended Use	Bipolar electrosurgical procedures	Same	Same
Configuration	Coated handle, bipolar connector, stainless Steel, Irrigation	Same	Same
Generator	Bipolar electrosurgical	Same	Same
Connector	2 pin bipolar, insulated	Same	Same
Materials	Nylon coated, stainless steel, plastic connector	Same	Same
Non Stick Tip	Silver Alloy	N/A	Same
Irrigation	Class VI PVC lumen	Same	
Sterilization	ETO	Same	
Safety	60601-2-2: Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment	Same	Same
Standards	ANSI/AAMI HF18-2001: Electrosurgical Devices	Same	Same

7. Conclusion: After analyzing bench and standards testing data of Stingray Electrosurgical Forceps K083162, and the comparison of Olsen Medical Single Use Bayonet Bipolar Irrigating Forceps K080187, it is the conclusion of Stingray Surgical Inc. that the Stingray Ultralite Disposable Irrigating Bipolar Forceps are as safe and effective as the predicate devices, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stingray Surgical Products Incorporated
% Mr. Brian McBrinn
Regulatory Affairs
801 Apple Tree Lane
Boca Raton, Florida 33486

NOV - 9 2011

Re: K102752
Trade/Device Name: Stingray Ultralite Disposable Irrigating Biopolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 2, 2011
Received: November 4, 2011

Dear Mr. McBrinn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Indications for Use

510(k) Number (if known): K102752

Device Name: Stingray Ultralite Disposable Irrigating Bipolar Forceps

Indications for Use:

Designed to grasp, manipulate and coagulate selected tissue for single use in general surgical procedures. These forceps can be sold with or without irrigation and are provided sterile. They are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator and irrigation module. Stingray Ultralite Disposable Irrigation Forceps can be used with bipolar coagulation current. Coagulation is achieved using electrosurgical energy generated by the electro surgical generator unit and activated by a footswitch. The Stingray Ultralite Disposable Irrigation Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102752